EXHIBIT J

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-1256 (LPS)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate"), by and through its attorneys, brings this Second Amended Complaint against Defendant Bionpharma Inc. ("Bionpharma"), and alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 10,772,868 ("'868 patent"), 10,786,482 ("'482 patent"), and 10,918,621 ("'621 patent") (collectively, "Patents-in-Suit") under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Bionpharma of Abbreviated New Drug Application ("ANDA") No. 212408 with the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral solution that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "Epaned® Product" or "Epaned®." Silvergate seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and other applicable laws for Bionpharma's infringement of the Patents-in-Suit.

2. This is also an action under 35 U.S.C. §§ 2201-2202 for a declaratory judgment of infringement of the '621 patent under 35 U.S.C. §§ 271 (a)-(c).

THE PARTIES

3. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801.

4. Silvergate is a wholly-owned subsidiary of Azurity Pharmaceuticals, Inc. ("Azurity").

5. On information and belief, Bionpharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 600 Alexander Road, #2-4B, Princeton, NJ 08540.

6. On information and belief, Bionpharma is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and from Bionpharma's submission of ANDA No. 212408.

8. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a). Relief is sought under 35 U.S.C. § 271(e)(2).

9. This Court has personal jurisdiction over Bionpharma because, among other things, and on information and belief, Bionpharma is a corporation formed under the laws of the State of Delaware.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

SILVERGATE'S EPANED® PRODUCT

11. Silvergate's Epaned® Product is an FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also

indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

12. Azurity is the holder of approved NDA No. 208686.

PATENTS-IN-SUIT

13. The ’868 patent, entitled “Enalapril Formulations,” issued on September 15, 2020 from United States Patent Application No. 16/242,898 (“’898 application”). A true and correct copy of the ’868 patent is attached to this Second Amended Complaint as Exhibit A.

14. The ’868 patent was duly and legally issued to Silvergate as the assignee. Silvergate owns all rights, title, and interest in the ’868 patent.

15. Pursuant to 21 U.S.C. § 355, the ’868 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) in connection with NDA No. 208686 (Silvergate’s Epaned® Product).

16. The ’482 patent, entitled “Enalapril Formulations,” issued on September 29, 2020 from United States Patent Application No. 16/177,159 (“’159 application”). A true and correct copy of the ’482 patent is attached to this Second Amended Complaint as Exhibit B.

17. The ’482 patent was duly and legally issued to Silvergate as the assignee. Silvergate owns all rights, title, and interest in the ’482 patent.

18. Pursuant to 21 U.S.C. § 355, the ’482 patent is listed in the Orange Book in connection with NDA No. 208686 (Silvergate’s Epaned® Product).

19. Silvergate’s Epaned® Product is covered by at least one claim of each of the ’868 and ’482 patents.

20. The ’621 patent, entitled “Enalapril Formulations,” issued on February 16, 2021 from United States Patent Application No. 16/991,575 (“’575 application”). A true and correct copy of the ’621 patent is attached to this Second Amended Complaint as Exhibit C.

21. The ’621 patent was duly and legally issued to Silvergate as the assignee. Silvergate owns all rights, title, and interest in the ’621 patent.

INFRINGEMENT BY BIONPHARMA

22. By letter dated October 30, 2018, Bionpharma notified Silvergate that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. §314.95, seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Silvergate’s Epaned® Product (“Bionpharma ANDA Product”) before the expiration of three Silvergate patents related to Epaned®: United States Patent Nos. 9,669,008 (“’008 patent”), 9,808,442 (“’442 patent”), and 10,039,745 (“’745 patent”)[1].

23. By a letter dated April 25, 2019, Bionpharma notified Silvergate that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of the Bionpharma ANDA Product before the expiration of another Silvergate patent: United States Patent No. 10,154,987 (“’987 patent”).[2]

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[1] On December 12, 2018, Silvergate brought an action against Bionpharma for infringement of the ’008 patent, ’442 patent, and ’745 patent in this District. That case is currently pending as C.A. No. 18-1962—trial for which took place February 1-5, 2021. Silvergate hereby incorporates by reference its Complaint (C.A. No. 18-1962, D.I. 1) against Bionpharma from that action.

[2] On June 7, 2019, Silvergate brought an action against Bionpharma for infringement of the ’987 patent in this District. That case, C.A. No. 19-1067, is also pending and proceeded on the same schedule as C.A. No. 18-1962. Silvergate hereby incorporates by reference its Complaint (C.A. No. 19-1067, D.I. 1) against Bionpharma from that action.

24. By two separate letters both dated December 4, 2020, Bionpharma notified Silvergate that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of the Bionpharma ANDA Product before the March 25, 2036 expiration of the '868 and '482 patents.

25. Each of the '008, '442, '745, '987, '868, '482, and '621 patents expire on March 25, 2036.

26. Upon information and belief, Bionpharma intends to engage in commercial manufacture, use, and sale of the Bionpharma ANDA Product promptly upon receiving FDA approval to do so.

27. Upon information and belief, Bionpharma is seeking approval to engage in the commercial manufacture, use, and sale of the Bionpharma ANDA Product before the expiration of the '868, '482, and '621 patents.

28. By filing ANDA No. 212408, Bionpharma has necessarily represented to FDA that the Bionpharma ANDA Product has the same active ingredients as Silvergate's Epaned® Product; has the same route of administration, dosage form, and strength as Silvergate's Epaned® Product; and is bioequivalent to Silvergate's Epaned® Product.

CLAIMS FOR RELIEF

Count I—Infringement of the '868 Patent Under 35 U.S.C. § 271(e)(2)(A)

29. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

30. Bionpharma submitted ANDA No. 212408 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma ANDA Product throughout the United States. By submitting the

ANDA, Bionpharma has committed an act of infringement of the '868 patent under 35 U.S.C. § 271(e)(2)(A).

31. If Bionpharma's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Bionpharma ANDA Product will constitute acts of infringement of the '868 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

32. On information and belief, Bionpharma has actual and constructive knowledge of the '868 patent and the '898 application. In addition, upon information and belief, Bionpharma has specific intent to infringe the '868 patent. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the '868 patent.

33. The commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma ANDA Product in violation of Silvergate's patent rights will cause irreparable harm to Silvergate for which damages are inadequate.

Count II—Infringement of the '482 Patent Under 35 U.S.C. § 271(e)(2)(A)

34. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

35. Bionpharma submitted ANDA No. 212408 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma ANDA Product throughout the United States. By submitting the ANDA, Bionpharma has committed an act of infringement of the '482 patent under 35 U.S.C. § 271(e)(2)(A).

36. If Bionpharma's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the

Bionpharma ANDA Product will constitute acts of infringement of the '482 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

37. On information and belief, Bionpharma has actual and constructive knowledge of the '482 patent and '159 application. In addition, upon information and belief, Bionpharma has specific intent to infringe the '482 patent. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the '482 patent.

38. The commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma ANDA Product in violation of Silvergate's patent rights will cause irreparable harm to Silvergate for which damages are inadequate.

Count III—Declaratory Judgment of Infringement of the '621 patent

39. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

40. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. There is an actual case or controversy such that the Court may entertain Silvergate's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

42. Bionpharma has refused to provide Silvergate with any advance notice of launch of the product that is the subject of Bionpharma's ANDA No. 212408.

43. On information and belief, Bionpharma will engage in and/or induce another to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Bionpharma's ANDA No. 212408 immediately and imminently upon approval of ANDA No. 212408.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Bionpharma's ANDA No. 212408 will constitute acts of infringement of the '621 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

45. The foregoing actions by Bionpharma will constitute infringement of the '621 patent.

46. Bionpharma will commit those acts of infringement without license or authorization.

47. Silvergate is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Bionpharma's ANDA No. 212408 by Bionpharma will infringe the '621 patent.

48. Silvergate does not have an adequate remedy at law.

49. The commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

PRAYER FOR RELIEF

Silvergate respectfully requests the following relief:

a) A judgment that Bionpharma has infringed the '868 and '482 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212408 under Section 505(j) of the FDCA, and that Bionpharma's making, using, offering to sell, or selling in the United States, or importing into the United States of the Bionpharma ANDA Product will infringe one or more claims of the '868 and '482 patents;

b) That a declaration be issued under 28 U.S.C. § 2201 that if Bionpharma, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of the product that is the subject of Bionpharma's ANDA No. 212408, it will constitute an act of infringement of the '621 patent under one or more of 35 U.S.C. § 271(a)-(c);

c) A finding that the Patents-in-Suit are valid and enforceable;

d) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 212408 shall be a date which is not earlier than the latest expiration date of the '868 and '482 patents, as extended by any applicable periods of exclusivity;

e) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Bionpharma, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, and/or importation into the United States, of any drug product covered by the '868 and '482 patents, including the Bionpharma ANDA Product;

f) An order under 35 U.S.C. § 283 permanently enjoining Bionpharma, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, and/or importation into the United States, of any drug product covered by the '621 patent, including the Bionpharma ANDA Product;

g) A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Silvergate be awarded reasonable attorneys' fees and costs; and

h) An award of any such other and further relief as the Court may deem just and proper.

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